



Iowa Board of Pharmacy

Published to promote compliance of pharmacy and drug law

400 SW 8th St, Suite E • Des Moines, IA 50309-4688 • Tel: 515/281-5944

Fax: 515/281-4609 • Website: <https://pharmacy.iowa.gov>

Is Your Pharmacy Participating?

By Sue Mears, RPh, Board Compliance Officer

During the 86th Iowa General Assembly, the Iowa legislature approved a law that allows pharmacists to dispense naloxone to individuals who may be in a position to assist someone experiencing an opioid-related overdose. The state's medical director, Dr Patricia Quinlisk, approved a statewide standing order for any pharmacy to use in order to provide this lifesaving medication. Iowa Board of Pharmacy rules were amended and became effective in November 2016. Since that time, the statewide order has been updated to include the newer formulation of the naloxone auto-injector. Also, the Recipient Eligibility Assessment form has had some updates, as recently as March 2017. If you are currently participating in the statewide standing order, please take a minute to review the updated forms on the Board's website to ensure you are using the most current form.

If you are not participating in the standing order, why not? Opioid abuse is a major problem, even in Iowa, and pharmacists are in a terrific position to provide assistance. If you are unsure of the need in your area, please take some time to check in with other providers or the police department in your local area. You may be surprised to find out the problem is in your backyard, too.

In order to assist the public in finding participating locations, Board staff would like to be notified if your pharmacy is participating in the statewide standing order. Please send a note to Sue Mears at sue.mears@iowa.gov to let the Board know of your pharmacy's participation.

Help Needed With USP Compliance Study

The Board needs your help with the largest and most comprehensive study of United States Pharmacopeia (USP) Chapters <797> and <800> compliance ever undertaken in the United States! The 2017 USP <797> & <800> Compliance Study, led by sterile compounding experts and study directors Eric Kastango, MBA, RPh, FASHP,

and Kate Douglass, MS, RN, CRNI, is now open. The study gives you the opportunity to perform a complete USP <797> and <800> gap analysis or answer questions related to just Chapter <797> or <800>, all from one login.

The study directors believe that the information and insights gained from this year's study will be very valuable to the industry. These results will assist with benchmarking progress and identify where additional resources and focus are required to continue to improve sterile compounding practice and patient safety. For that reason, you are encouraged to participate.

The study uses a sophisticated, web-based gap analysis tool that Ms Douglass and Mr Kastango developed and have been using for the last several years. This tool is being made available at **no charge** to all study participants. It should be noted that **all individual facility results are confidential – only aggregate data will be used in the study report.**

In return for your participation, you will receive a highly detailed action plan that is automatically generated based on your answers to the survey. This action plan provides documentation that can be used to begin or continue sterile compounding practice improvements at your location. The survey takes 60 to 90 minutes to complete, but does not need to be completed in one sitting. This year, the study team has also provided a pdf document of all the questions to facilitate offline data collection for those who might find this useful. This will be available for download after you have registered and completed the first two informational sections of the survey.

Please register for the study today at <http://797study.criticalpoint.info>. Use survey code G797A. The study will remain open through June 30, 2017.

Thank you in advance for your participation in the 2017 USP <797> & <800> Compliance Study. The results will help the Board learn more about the successes and challenges relative to USP <797> and <800> compliance. With that

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DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- ◆ If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- ◆ DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- ◆ Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at www.deadiversion.usdoj.gov/drugreg/index.html.

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the

ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit <https://www.ismp.org/Survey/NewMssacap/Index.asp>.

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists*, CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at www.cdc.gov/dhbsp/pubs/docs/pharmacist-resource-guide.pdf.

News to a particular state or jurisdiction can only be ascertained
such state or jurisdiction.

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at <https://jcphp.net>.

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf.

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register*, which can be found at www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed

to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at www.ptcb.org in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit www.BuySafeRx.pharmacy.

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at <http://lawatlas.org/datasets/pharmacist-vaccination>, explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

insight, it becomes easier to target additional strategies to promote best-practice sterile compounding. The results of the study will be published this fall in *Pharmacy Purchasing & Products*.

If you have any questions, please contact the study team at studyteam@797study.com.

CARA 2016 – Partial Filling of a Schedule II

By Sue Mears, RPh, Board Compliance Officer

In July 2016, US Congress passed the Comprehensive Addiction and Recovery Act (CARA), which President Obama signed into law. The law adds a provision that allows pharmacists to partially fill any Schedule II prescription at the request of the prescriber or the patient, as long as state law does not prohibit such partial filling. CARA language allows the remaining portion of the partially filled prescription to be filled within 30 days of the date the prescription was issued.

Currently, Iowa Code would not prohibit such partial filling, but the Board's rules do not have a specific provision to allow the filling of the remaining portion of the prescription at this time. The Board is in the process of reviewing and updating Chapter 10 and plans to include the CARA language. While the Board's rule currently does not specifically identify this scenario for partial filling of a Schedule II prescription, a pharmacy that is complying with the provisions in CARA would not be in conflict with Iowa Code or Board rules.

New Database on the Way for Board of Pharmacy – Update!

Board executive and administrative staff, via the Iowa Department of Administrative Services (DAS), has identified a vendor to supply and configure a new licensing database to meet the technological needs of the public as well as Board staff. A Notice of Intent to Award was sent by DAS to iGov Solutions, LLC (Lake Mary, FL) on April 7, 2017. The Board hopes to begin implementation and data migration in the coming months. The Board projects that pharmacists due to renew their licenses in June 2018 will be able to do so online.

Iowa 2017 Legislative Update

The Iowa legislature has concluded its 2017 session. The following bills have been passed and signed into law that may be of interest to the pharmacy community:

- ◆ **Senate File (SF) 484** was the Board's proposed bill to amend Iowa Code 155A, which would permit the Board to designate alternate Board members to serve during contested case proceedings when a quorum of the Board is unable to be obtained. This bill also removed the spending cap placed on the Board's prescription drug take-back program.
- ◆ **SF 332** was the Board's proposed bill to amend Iowa Code 124 to incorporate federal schedule changes into Iowa law. This included the transition of tramadol from legend status to Schedule IV status and hydrocodone-containing products from Schedule III status to Schedule II. Practically speaking, this legislative change will not impact the practice of pharmacy in Iowa, since these products have already been designated to these statuses at the federal level.
- ◆ **House File 524** amends Iowa Code 124 to expand prescription monitoring program information sharing to any state (currently, information is only shared with bordering states and Kansas). This bill also expands medical cannabidiol to treat multiple disease states, and allows up to two manufacturers and five dispensaries in Iowa.

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Andrew Funk, PharmD - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

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